

occur as a result of the manufacturing process itself, there shall be written procedures describing any processing controls necessary to assure conformance to specifications.

(2) All processing control operations shall be conducted in a manner designed to assure that the device conforms to applicable specifications.

(3) There shall be a formal approval procedure for any change in the manufacturing process of a device. Any approved change shall be communicated to appropriate personnel in a timely manner.

§ 820.101 Critical devices, manufacturing specifications, and processes.

In addition to the requirements of § 820.100, the following requirements apply to critical devices:

(a) *Critical operation performance.* Any critical operation shall be performed by a suitable designated individual(s) or suitable equipment and shall be verified.

(b) *Record of critical operation.* Any individual responsible for the performance of a critical operation shall record or reference that operation in the device history record as required in § 820.185.

§ 820.115 Reprocessing of devices or components.

(a) Reprocessing procedures shall be established, implemented, and controlled to assure that the reprocessed device or component meets the original, or subsequently modified and approved, specifications.

(b) Any device rejected during finished device inspection and later reprocessed shall be subject to another complete final inspection for any characteristic of the device which may be adversely affected by such reprocessing.

§ 820.116 Critical devices, reprocessing of devices or components.

In addition to the requirements of § 820.115, the following requirements apply to critical devices:

(a) *Reprocessing procedures.* There shall be written procedures for any reprocessing associated with the production of a critical device or component. These procedures shall prescribe the

equipment to be used in reprocessing and shall include any special quality assurance methods or tests. The procedures shall be designed so that the reprocessed device or component meets the original, or subsequently modified and approved, specifications. The procedures shall be designed to prevent adulteration, e.g., because of material, structural, or molecular change in the device or component due to reprocessing. Special care shall be taken to assure that the device or component to be reprocessed is clearly identified and separated from like devices or components not to be reprocessed. When there is constant reprocessing of a device or component, a determination of the effect of the reprocessing upon the device or component shall be made and documented. There shall be a formal approval procedure for instituting a new, or altering an approved, reprocessing procedure.

(b) *Reprocessing control.* Any critical device or component subject to reprocessing procedures shall conform to the original, or subsequently modified and approved, specifications. Written testing and sampling procedures to assure such conformity shall be contained or referenced in the device master record. Any prior quality assurance check shall be repeated on the reprocessed device or component if the reprocessing could adversely affect any performance characteristic previously inspected.

Subpart G—Packaging and Labeling Control

§ 820.120 Device labeling.

There shall be adequate controls to maintain labeling integrity and to prevent labeling mixups.

(a) *Label integrity.* Labels shall be designed, printed, and applied so as to remain legible during the customary conditions of processing, storage, handling, distribution, and use. Labels and other labeling shall not be released to inventory until a designated individual has proofread samples of the labeling for accuracy.

(b) *Separation of operations.* Each labeling or packaging operation shall be separated physically or spatially in a manner designed to prevent mixups.